GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE

Working Group Chair: Melissa Torres
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GOALS

• The Good Regulatory Review Practices working group has focused efforts on harmonizing premarket requirements in alignment with the IMDRF strategic priority to improve the effectiveness and efficiency of premarket review.

• First completed work item:
  – IMDRF GRRP WG/N40FINAL: 2017 “Competence, Training, and Conduct Requirements for Regulatory Reviewers”
    • Defines a common set of conduct, education, experience, competence, and training requirements for premarket reviewers.
CURRENT WORK ITEM

- A NWIP was approved during the March 2017 IMDRF MC meeting which focused on revising GHTF/SG1/N68:2012 *Essential Principles of Safety and Performance of Medical Devices* to create a new/updated IMDRF document outlining essential principles that can be used as a foundation for creating a more harmonized premarket review process.
  - New requirements
  - New standards
CURRENT PROGRESS

- Face-to-face working group meeting was held in Silver Spring, MD from July 10-13, 2017.
- WG used EU MDR, ISO 16142, and other jurisdictional requirements to update the Essential Principles.
- An initial draft of the Essential Principles document was created during the meeting.
- Draft document was circulated internally among WG participants and their jurisdiction.
  - Initial comments were received and incorporated.
- WG will begin working on guidance for the essential principles.
NWIP

NWIP was submitted to IMDRF MC for consideration to revise GHTF *Label and Instructions for Use for Medical Devices* (GHTF/SG1/N70:2011)

- Updating the labelling and instructions for use document in conjunction with the Essential Principles document is necessary given technological and regulatory developments since its original publication.
- Revisions will be based on EU MDR, ISO 16142, and jurisdictional requirements.
**Next Steps**

- If approved, GRRP WG will proceed with revision to GHTF/SG1/N70:2011 in conjunction with revisions to the Essential Principles (GHTF/SG1/N68:2012) aiming to have both documents completed for public consultation in Feb/March 2018.
IMDRF International Medical Device Regulators Forum

**TIMELINE**

- **Working Group Forms and Reviews Existing EP Documents**: May - July 2017
- **Face to Face Meeting**: TBD
  - Silver Spring, MD
  - July 2017
- **Proposed Working Draft Documents Submitted to MC**: Jan 2018
- **Proposed Documents out for Public Consultation**: Feb/March 2018
- **Face to Face Meeting**: TBD
  - May 2018
- **Face to Face Meeting**: TBD
  - Nov/Dec 2018
- **Submit Final Documents to MC**: Sept 2018
- **Working group teleconferences**
THANK YOU